Attorney's Docket No.: 17737-003US1/3703US

Applicant: Thomas Julius Borody, et al.

Serial No.:

Filed: September 2, 2004

Title: ELECTROLYTE PURGATIVE

AMENDMENTS TO THE CLAIMS:

Please amend claims 1, 10-19 and 22-30. Please add new claims 31 - 36. This listing of claims replaces all prior versions, and listings of claims, in the application.

LISTING OF CLAIMS:

- 1. (currently amended) A composition for use in a purgative, the composition comprising:
 - (i) at least one water-soluble sodium salt;
 - (ii) at least one water-soluble minimally degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium ions in said composition;
 - (iii) at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of said sodium salt in said composition; and
 - [[(v)]] (iv) at least one water-soluble magnesium salt, wherein the weight of magnesium ions in said composition is from about 0.1 to about 10 times the weight of sodium ions in said composition.
- 2. (original) The composition of claim 1, wherein the minimally degradable sugar is selected from the group consisting of xylose, xylotriose, xylooligosaccharides, fructooligosaccharides, fructosans, galactooligosaccharides, other oligosaccharides, and mixtures thereof.
- 3. (original) The compositions of claim 1, wherein the water-soluble sodium salt is selected from the group consisting of sodium chloride, sodium gluconate, sodium citrate, sodium asparate and mixtures thereof.
- 4. (original) The composition of claim 1, wherein the water-soluble potassium salt is selected from the group consisting of potassium chloride and potassium tartrate.
- 5. (original) The composition of claim 1, wherein the water-soluble magnesium salt is selected from the group consisting of magnesium sulfate, magnesium citrate and magnesium phosphate.
- 6. (original) The composition of claim 1 further comprising at least one additive selected from the group consisting of a flavouring ingredient, a detergent stool-softening agent, citrate, lactate, acetate, trace elements and nutritional elements.
- 7. (original) The composition of claim 1 in the form of a soup or soup-like composition, tablet, gel cap, capsule or sachet.

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8. (original) A purgative, comprising a hypertonic aqueous solution of the composition of claim 1.

- 9. (original) The purgative of claim 8 in the form of a unit dose having a volume of from about 0.2 to 0.5L and wherein the sodium salt or salts are present in an amount from about 1 to about 10g per unit dose, the minimally degradable sugar or sugars in an amount of from about 2 to about 20g, the potassium salt or salts in an amount of from about 0.5 to about 5g and the magnesium salt or salts in an amount of from about 1 to about 10g per unit dose of the purgative.
- 10. (currently amended) A method of inducing purgation of the colon of a patient in need thereof, comprising administering to said patient a composition of claim 1 or a purgative of claim 10 in an amount effective to induce purgation of the patient's colon.
- 11. (currently amended) The use of a composition of claim 1 for the manufacture of a purgative for A method of inducing purgation of the colon of a patient in need thereof, comprising administering to the patient a composition of a purgative of claim 8 in an amount effective to induce purgation of the patient's colon.
- 12. (currently amended) A method for treatment or prevention of one or more of a member selected from the group consisting of lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache and convulsions, comprising administering to a patient in need of such treatment a composition of claim 1 or a purgative of claim 8, whereby lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions is treated or prevented.
- 13. (currently amended) Use of a composition of claim 1 for the manufacture of a medicament for the A method for treatment or prevention of one or more of a member selected from the group consisting of lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache and convulsions, comprising administering to a patient in need of such treatment a purgative of claim 8, whereby lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions is treated or prevented.
- 14. (currently amended) A method for the treatment or prevention of acute gastrointestinal infections, comprising administering to a patient in need of such treatment a composition of claim 1 or a purgative of claim 8, whereby acute gastrointestinal infection is treated or prevented.

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15. (currently amended) Use of a composition of claim 1 for the manufacture of a medicament A method for the treatment or prevention of acute gastrointestinal infections, comprising administering to a patient in need of such treatment a purgative of claim 8, whereby acute gastrointestinal infection is treated or prevented.

- 16. (currently amended) A method for the treatment or prevention of constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome, comprising administering to a patient in need of such treatment a composition of claim 1 or a purgative of claim 8, whereby constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome is treated or prevented.
- 17. (currently amended) Use of a composition of claim 1 for the manufacture of a medicament A method for the treatment or prevention of constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome, comprising administering to a patient in need of such treatment a purgative of claim 8, whereby constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome is treated or prevented.
- 18. (currently amended) The composition of claim 1 or the purgative of claim 8 when used in A method for pre-colonoscopic or pre-surgical lavage, comprising administering to a patient a composition of claim 1 as a simple purgative, as electrolyte replacement lavage, as a barium enema preparation, in CT "virtual colonoscopy", in radiological applications, as electrolyte replacement lavage solutions, as electrolyte replacement lavage solutions for acute gastrointestinal infections, for symptomatic treatment in patients suffering from acute or chronic constipation or related symptoms or constipation predominant irritable bowel syndrome, as a regular laxative, or for the treatment or prevention of lavage associate hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.
- 19. (currently amended) A composition for use in a purgative, the composition comprising:
 - (i) at least one water-soluble sodium salt;
 - (ii) at least one water-soluble degradable sugar in an amount, by weight, of from about 1 to about 3 times the weight of sodium ions in said composition;

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(iii) at least one water-soluble potassium salt in an amount, by weight, of from about 0.05 to about 1 times the weight of said sodium salt in said composition; and

[[(vi)]] (iv) at least one water-soluble magnesium salt, wherein the weight of magnesium ions in said composition is from about 0.1 to about 10 times the weight of sodium ions in said composition.

- 20. (original) A composition of claim 19 wherein the degradable sugar is selected from the group consisting of glucose, L-glucose, sucrose, fructose, galactose, lactose, mannitol and lactulose.
- 21. (original) A purgative, comprising a hypertonic aqueous solution of the composition of claim 19.
- 22. (currently amended) A method of inducing purgation of the colon of a patient in need thereof, comprising administering to said patient in the absence of diathermy a composition of claim 19 or a purgative of claim 21 in an amount effective to induce purgation of the patient's colon.
- [[22.]] 23. (currently amended) The use of a composition of claim 19 for the manufacture of a purgative for A method of inducing purgation of the colon of a patient in need thereof, comprising administering to the patient in the absence of diathermy a purgative of claim 21 in an amount effective to induce purgation of the patient's colon.
 [[23.]] 24. (currently amended) A method for the treatment or prevention of one or more of a member selected from the group consisting of lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache and convulsions, comprising administering to a patient in need of such treatment in the absence of diathermy a composition of claim 19 or a purgative of claim 21, whereby lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions are treated or prevented.
- [[24.]] 25. (currently amended) Use of a composition of claim 19 for the manufacture of a medicament A method for the treatment or prevention in the absence of diathermy of one or more of a member selected from the group consisting of lavage-associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache and convulsions, comprising administering to a patient in need of such treatment in the absence of diathermy a composition of a purgative of claim 21, whereby lavage-associated

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hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions are treated or prevented.

[[25.]] 26. (currently amended) A method for the treatment or prevention of acute gastrointestinal infections, comprising administering to a patient in need of such treatment in the absence of diathermy a composition of claim 19 or a purgative of claim 21, whereby acute gastrointestinal infection is treated or prevented.

[[26.]] 27. (currently amended) Use of a composition of claim 19 for the manufacture of a medicament A method for the treatment of prevention of acute gastrointestinal infections, comprising administering to a patient in need of such treatment in the absence of diathermy a purgative of claim 21, whereby acute gastrointestinal infection is treated or prevented.

[[27.]]28. (currently amended) A method for the treatment or prevention of constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome, comprising administering to a patient in need of such treatment in the absence of diathermy a composition of claim 19 or a purgative of claim 21, whereby constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome is treated or prevented.

[[28.]]29. (currently amended) Use of a composition of claim 19 for the manufacture of a medicament A method for the treatment or prevention of constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome, comprising administering to a patient in need of such treatment in the absence of diathermy a purgative of claim 21, whereby constipation, acute constipation, chronic constipation or constipation predominant irritable bowel syndrome is treated or prevented.

[[29.]]30. (currently amended) The composition of claim 19 or the purgative of claim 21 when used in the absence of diathermy in A method for pre-colonoscopic or presurgical lavage, comprising administering to a patient in the absence of diathermy a composition of claim 19 as a simple purgative, as electrolyte replacement lavage, as a barium enema preparation, in CT "virtual colonoscopy", in radiological applications, as electrolyte replacement lavage solutions, as electrolyte replacement lavage solutions for acute gastrointestinal infections, for symptomatic treatment in patients suffering from acute or chronic constipation or related symptoms or constipation predominant irritable bowel syndrome, as a regular laxative, or for the treatment of prevention of lavage-

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associated hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.

31. (new) The method of claim 30, wherein the method is selected from among a simple purgative, an electrolyte replacement lavage, a barium enema preparation, a CT "virtual colonoscopy", a radiological application, an electrolyte replacement lavage, an electrolyte replacement lavage for acute gastrointestinal infection, a treatment for acute or chronic constipation and related symptoms or a treatment for constipation predominant irritable bowel syndrome, a regular laxative, or a treatment or prevention of lavage-associate hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.

- 32. (new) A method for pre-colonoscopic or pre-surgical lavage, comprising administering to a patient in the absence of diathermy a purgative of claim 21.
- 33. (new) The method of claim 32, wherein the method is selected from among a simple purgative, an electrolyte replacement lavage, a barium enema preparation, a CT "virtual colonoscopy", a radiological application, an electrolyte replacement lavage, an electrolyte replacement lavage for acute gastrointestinal infection, a treatment for acute or chronic constipation and related symptoms or a treatment for constipation predominant irritable bowel syndrome, a regular laxative, or a treatment or prevention of lavage-associate hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.
- 34. (new) A method for pre-colonoscopic or pre-surgical lavage, comprising administering to a patient a purgative of claim 8.
- 35. (new) The method of claim 34, wherein the method is selected from among a simple purgative, an electrolyte replacement lavage, a barium enema preparation, a CT "virtual colonoscopy", a radiological application, an electrolyte replacement lavage, an electrolyte replacement lavage for acute gastrointestinal infection, a treatment for acute or chronic constipation and related symptoms or a treatment for constipation predominant irritable bowel syndrome, a regular laxative, or a treatment or prevention of lavage-associate hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.
- 36. (new) The method of claim 18, wherein the method is selected from among a simple purgative, an electrolyte replacement lavage, a barium enema preparation, a CT "virtual colonoscopy", a radiological application, an electrolyte replacement lavage, an

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electrolyte replacement lavage for acute gastrointestinal infection, a treatment for acute or chronic constipation and related symptoms or a treatment for constipation predominant irritable bowel syndrome, a regular laxative, or a treatment or prevention of lavage-associate hyponatremia, hypoosmolality, nausea, malaise, vomiting, headache or convulsions.